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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)	
	10/598,117	HARRIS, CRAIG STEVEN	
Office Action Summary	Examiner	Art Unit	
	CRAIG RICCI	4161	
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet with the o	correspondence address	
A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory perions are reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION 1.136(a). In no event, however, may a reply be tile of will apply and will expire SIX (6) MONTHS from the, cause the application to become ABANDONE	N. mely filed I the mailing date of this communication. ED (35 U.S.C. § 133).	
Status			
1) ☐ Responsive to communication(s) filed on 17 2a) ☐ This action is FINAL. 2b) ☐ This action is FINAL. 2b) ☐ This action is application is in condition for allow closed in accordance with the practice under	nis action is non-final. vance except for formal matters, pro		
Disposition of Claims			
4) ☐ Claim(s) 1-16 is/are pending in the application 4a) Of the above claim(s) is/are withdrest is/are allowed.  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) 1-16 are subject to restriction and/or	rawn from consideration.		
Application Papers			
9) The specification is objected to by the Examination The drawing(s) filed on is/are: a) and applicant may not request that any objection to the Replacement drawing sheet(s) including the correction.  11) The oath or declaration is objected to by the least or the specific structure.	ccepted or b) objected to by the ne drawing(s) be held in abeyance. Se ection is required if the drawing(s) is ob	e 37 CFR 1.85(a). ejected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:      1. ☐ Certified copies of the priority docume 2. ☐ Certified copies of the priority docume 3. ☐ Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a limit	nts have been received. nts have been received in Applicat iority documents have been receiv au (PCT Rule 17.2(a)).	ion No ed in this National Stage	
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail D 5)  Notice of Informal F 6)  Other:	ate	

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## DETAILED ACTION

## Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 2-6, 8-12, 14 and 16 drawn to a compound of the formula

$$R^5$$
 $R^4$ 
 $R^1$ 

wherein R<sup>2</sup> is 3,5-dimethylphenyl-; R<sup>3</sup> is Formula (IIa) or (IIb);

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B is Formula (IV); and  $R^5$  is

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Group II, claim(s) 2-6, 8-11, 14 and 16 drawn to a compound of the formula

$$R^5$$
 $M$ 
 $R^4$ 
 $R^1$ 

wherein R<sup>2</sup> is 3,5-dimethylphenyl-; R<sup>3</sup> is Formula (IIa) or (IIb);

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B is  $\underline{\text{not}}$  Formula (IV); and  $R^5$  is

Group III, claim(s) 2-11, 14 and 16, drawn to a compound of the formula

$$R^5$$
 $R^4$ 
 $R^1$ 

wherein  $R^2$  is 3,5-dimethylphenyl-;  $R^3$  is Formula (IIc) or (IId);

J is -(CH<sub>2</sub>)<sub>s</sub>-L-(CH<sub>2</sub>)<sub>s</sub>; and  $R^5$  is

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Group IV, claim(s) 2-11, 14 and 16 drawn to a compound of the formula

wherein R<sup>2</sup> is 3,5-dimethylphenyl-; R<sup>3</sup> is Formula (IIc) or (IId);

J is -(CH<sub>2</sub>)  $_s$ -C(O)-(CH<sub>2</sub>)  $_s$ -L-(CH<sub>2</sub>)  $_s$ ; and R<sup>5</sup> is

Group V, claim(s) 2-11, 13-14 and 16, drawn to a compound of the formula

$$R^5$$
 $R^4$ 
 $R^3$ 
 $R^2$ 

wherein  $R^2$  is 3,5-dimethylphenyl-;  $R^3$  is Formula (IIc) or (IId);

the group

together forms an optionally substituted heterocyclic ring; and

R<sup>5</sup> is

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Group VI, claim(s) 2-14, drawn to a compound of the formula

wherein R<sup>2</sup>, R<sup>3</sup>, and R<sup>5</sup> are **not** defined as above for any

Groups I – V.

Group VII, claim(s) 1 drawn to a method of using the compound of the formula

$$R^5$$
 $M$ 
 $R^4$ 
 $R^1$ 

wherein R<sup>2</sup> is 3,5-dimethylphenyl-; R<sup>3</sup> is Formula (IIa) or (IIb);

B is Formula (IV); and R<sup>5</sup> is

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Group VIII, claim(s) 1 drawn to a method of using the compound of the formula

$$R^5$$
 $R^4$ 
 $R^3$ 
 $R^2$ 
 $R^4$ 
 $R^1$ 

wherein R<sup>2</sup> is 3,5-dimethylphenyl-; R<sup>3</sup> is Formula (IIa) or (IIb);

B is **not** Formula (IV); and R⁵ is

Group IX, claim(s) 1, drawn to a method of using the compound of the formula

$$R^5$$
 $R^4$ 
 $R^1$ 

wherein  $R^2$  is 3,5-dimethylphenyl-;  $R^3$  is Formula (IIc) or (IId);

J is -(CH<sub>2</sub>)<sub>s</sub>-L-(CH<sub>2</sub>)<sub>s</sub>; and  $R^5$  is

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Group X, claim(s) 1 drawn to a method of using the compound of the formula

$$R^5$$
  $R^4$   $R^3$   $R^2$ 

wherein R<sup>2</sup> is 3,5-dimethylphenyl-; R<sup>3</sup> is Formula (IIc) or (IId);

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J is  $-(CH_2)_s$ -C(O)- $(CH_2)_s$ -L- $(CH_2)_s$ ; and  $R^5$  is

Group XI, claim(s) 1, drawn to a method of using the compound of the formula

$$R^5$$
 $R^4$ 
 $R^1$ 

wherein R<sup>2</sup> is 3,5-dimethylphenyl-; R<sup>3</sup> is Formula (IIc) or (IId);

the group

together forms an optionally substituted heterocyclic ring; and

R<sup>5</sup> is

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Group XII, claim(s) 1, drawn to a method of using the compound of the formula

wherein  $R^2$ ,  $R^3$ , and  $R^5$  are <u>not</u> defined as above for any

Groups VI - XI

**Group XIII**, claim(s) 15, drawn to a method of making the inventions of Groups I-V. Applicant is advised that Group VI, if elected, may be subject to further restriction.

- 2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." Moreover, as stated in PCT Rule 13.2, "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."
- 3. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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Groups VI are drawn to compounds of the formula

$$R^5$$
 $R^4$ 
 $R^3$ 
 $R^2$ 

wherein the variable groups R¹-R⁵ and M are defined in the claim. Given the substantial number of possibilities for each variable group R¹-R⁵ and M, including the possibility that each variable group can include additional variable groups which further can include even more variable groups and so on, it is clear that Group VI encompasses literally millions of potential compounds. As such, the only special technical feature shared between the Groups I-XIII is their pyrrole core. The pyrrole core of claim 1 does not present a contribution over the prior art. As disclosed in *Kawai et al* (WO 98/02430) (abstract) provided by Applicant, the pyrrole core of instant claim 1 is anticipated. As such, Group VI does not share a special technical feature with the instant claims of Group I-V and XIII. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-XIII is broken.

4. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## Election of Species

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If any of Group I-XIII is elected, the following species election is required:

a) A single compound species recited by claims 1-14;

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, as to claims 1-14, Applicant is required to elect a single compound species from the numerous possible species for examination, and as to that species, Applicant is required to define each of R<sup>1</sup>-R<sup>5</sup>, M and every additional variable as required for that particular species (a species for example is methyl, NOT alkyl). Accordingly, upon Applicant's election of species, the result must provide a single chemical species. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner: claims 3-6, 8-12, 14 as to Group I; claims 2-6, 8-11, 14 as to Group II; claims 2-11, 14 as to Groups III and IV; claims 2-11, 13-14 as to Group V; and claims 2-14 as to Group VI. The following claim(s) are generic: claims 2 and 16 as to Groups I-VI; claim 1 as to Groups VII-XII and claims 15 as to Group XIII.

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7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

a) each chemical species is a distinct chemical which lacks a special technical feature in view of *Kawai et al* (WO 98/02430) (abstract)

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the

requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571)270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/ Examiner, Art Unit 4161

/Patrick J. Nolan/ Supervisory Patent Examiner, Art Unit 4161